

## Food and Drug Administration, HHS

## § 522.2404

### § 522.2260 Sulfamethazine.

(a) *Specifications.* Each milliliter (mL) of solution contains 250 milligrams (mg) sulfamethazine sodium.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use in cattle—(1) Amount.* Initially administer 20 mL for each 50 pounds (lb) of body weight (100 mg/lb) by intravenous injection, followed by 20 mL per 100 lb of body weight (50 mg/lb) by intravenous injection, daily thereafter. Treatment should not exceed a total of 5 consecutive days.

(2) *Indications for use.* For cattle for treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis and acute metritis (*Streptococcus* spp.) when caused by one or more pathogenic organisms sensitive to sulfamethazine.

(3) *Limitations.* Withdraw medication from cattle 10 days prior to slaughter. Do not use in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 62055, Dec. 22, 1981, as amended at 67 FR 78355, Dec. 24, 2002; 75 FR 10167, Mar. 5, 2010; 76 FR 53051, Aug. 25, 2011]

### § 522.2340 Sulfomyxin.

(a) *Specifications.* Sulfomyxin for injection is sterile. It is derived from the antibiotic substance produced by the growth of *Bacillus polymyxa* or is the same substance produced by any other means.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Special considerations.* The quantities of antibiotic in paragraph (e) of this section refer to the activity of the appropriate standard.

(d) *Related tolerances.* See § 556.700 of this chapter.

(e) *Conditions of use.* (1) It is used or intended for use in chickens and turkeys as an aid in the treatment of disease caused or complicated by *E. coli*,

such as colibacillosis and complicated chronic respiratory disease.

(2) It is administered by subcutaneous injection as follows:

Age of birds in days	Antibiotic activity	
	Chickens (units)	Turkeys (units)
1 to 14 .....	12,500	12,500
15 to 28 .....	25,000	25,000
29 to 63 .....	50,000	50,000
Over 63 .....	50,000	100,000

(3) A second injection may be given 3 days later if symptoms persist.

(4) Not for use in laying hens; do not treat chickens within 5 days of slaughter; do not treat turkeys within 7 days of slaughter.

[40 FR 13858, Mar. 27, 1975, as amended at 79 FR 16196, Mar. 25, 2014]

### § 522.2404 Thialbarbitone sodium for injection.

(a) *Specifications.* Thialbarbitone sodium for injection when reconstituted with sterile distilled water provides 94 milligrams of thialbarbitone sodium per milliliter of solution.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered as a general anesthetic in surgical procedures on dogs, cats, swine, sheep, cattle, and horses. The drug is used for procedures of relatively short duration. However, the period of anesthesia can be lengthened by slower initial injection and supplemental administration during surgery.

(2) It is administered intravenously. The drug is injected slowly to dogs, cats, cattle, sheep, and swine. For horses, it is recommended that a pre-anesthetic sedation be administered to the horse 30 minutes before the drug is administered. The drug is then injected rapidly and completely. The drug is used at the following dosage levels:

Species	Weight of animal in pounds	Dosage in milligrams per pound
Dog .....	Over 50 .....	14.1
Do .....	30–50 .....	18.8
Do .....	10–30 .....	23.5
Do .....	Under 10 .....	28.2
Cat .....	.....	31.3–37.6
Horse .....	.....	6.3–7.8
Cattle and swine .....	.....	6.7–9.4
Calves and sheep .....	.....	9.4–11.8

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(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 79 FR 16196, Mar. 25, 2014]

### § 522.2424 Thiamylal.

(a) *Specifications.* The drug is a sterile powder. It is reconstituted with sterile distilled water, water for injection, or sodium chloride injection, to a desired concentration of 0.5 to 4 percent sodium thiamylal.

(b) *Sponsors.* See Nos. 054628 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer by intravenous injection to effect. The average single dose is:

(i) *Dogs and cats:* 8 milligrams (mg) per pound of body weight (when used with a preanesthetic, generally one-half the normal dose).

(ii) *Swine:* 40 mg per 5 pounds (lbs) of body weight.

(iii) *Horses:* Light anesthesia, 1 gram per 500 lbs to 1,100 lbs of body weight; deep anesthesia, 1 gram per 300 lbs of body weight (40 mg/12 lbs of body weight).

(iv) *Cattle:* Short duration, 20 mg/5 lbs of body weight; longer duration, 40 mg/7 lbs of body weight.

(2) *Indications for use.* It is used as an ultra-short-acting anesthetic in dogs, cats, swine, horses, and cattle.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16196, Mar. 25, 2014]

### § 522.2444 Thiopental injectable dosage forms.

#### § 522.2444a Thiopental powder for injection.

(a) *Specifications.* The drug contains sodium thiopental powder for constitution with sterile water for injection.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer by intravenous injection as follows:

(i) 6 to 9 milligrams (mg) per pound of body weight for brief anesthesia (6 to 10 minutes).

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(ii) 10 to 12 mg per pound of body weight for anesthesia of 15 to 25 minutes duration.

(2) *Indications for use.* It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical and other procedures. It is also used to induce anesthesia in dogs and cats which then have surgical anesthesia maintained by use of a volatile anesthetic.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16196, Mar. 25, 2014]

### § 522.2444b Thiopental and pentobarbital powder for injection.

(a) *Specifications.* Each gram of powder contains 750 milligrams (mg) of sodium thiopental and 250 mg of sodium pentobarbital powder for dilution with sterile water for injection.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For total anesthesia, it is given at approximately 10 to 12 mg per pound of body weight over a period of 3.5 to 5 minutes. When preanesthetic medication is used, wait at least an hour before administering thiopental and sodium pentobarbital for injection, and the dosage necessary for anesthesia is reduced. Usually  $\frac{1}{2}$  to  $\frac{2}{3}$  the normal amount is adequate.

(2) *Indications for use.* It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical procedures.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16197, Mar. 25, 2014]

### § 522.2460 Tildipirosin.

(a) *Specifications.* Each milliliter of solution contains:

(1) 180 milligrams (mg) tildipirosin.

(2) [Reserved]

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.733 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer 4 mg/kg of body weight one time by subcutaneous injection in the neck.